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Re: Patent Term Extension
Application for
U.S. Patent No. 4,996,335

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,996,335, which claims the human drug product loteprednol etabonate (LOTEMAX™ and ALREX®), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,473 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 1,473 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of May 18, 1999 (64 Fed. Reg. 26986). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} \text{ (Testing Phase)} + \text{Approval Phase} \\ &= \frac{1}{2} (2,017 - 522) + 1,075 \\ &= 1,823 \text{ days}\end{aligned}$$

Since the regulatory review period began September 22, 1989, before the patent issued (February 26, 1991), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From September 22, 1989 to February 26, 1991 is 522 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,823 days, would extend the patent from February 26, 2008 (35 U.S.C. § 154) to February 22, 2013, which is beyond the 14-year limit (the approval date is March 9, 1998, thus the 14 year limit is March 9, 2012). The period of extension is thus limited to March 9, 2012, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, February 26, 2008, to and including March 9, 2012, or 1,473 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 4,996,335

Granted: February 26, 1991
Original Expiration Date¹: February 26, 2008
Applicant: Nicholas S. Bodor
Owner of Record: Nicholas S. Bodor
Title: Soft-Steroids Having Anti-Inflammatory Activity
Classification: 552/610
Product Trade Name: LOTEMAX™ and ALREX® (loteprednol etabonate)
Term Extended: 1,473 days
Expiration Date of Extension: March 9, 2012

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

Telephone inquiries related to this determination should be directed to the undersigned
at (703) 306-3159.



Karin L. Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: LOTEMAX™ and ALREX®
FDA Docket No.: 98E-0789

¹Subject to the provisions of 35 U.S.C. § 41(b).